III. REMARKS

Preliminary Remarks

Claims 1 - 17 are pending in the present application, of which claims 1 and 5 are independent. Claim 18 has been withdrawn from consideration. In the outstanding Office Action the oath/declaration was asserted to be defective; claims 1, 3, 4, 7, 8, 12, and 13 were rejected under 35 U.S.C. § 102(b); and claims 1-17 were rejected under 35 U.S.C. § 103(a). The applicants respectfully request reconsideration and allowance of the present application.

Oath/Declaration

The oath/declaration was considered defective because of non-initialed alterations to the last inventors address. As discussed with the Examiner on June 22, 2004 the attached declaration states that the changes to the last inventor's address were made prior to the last inventor signing the declaration. Accordingly, the declaration is not defective.

Patentability Remarks

Rejection under 35 U.S.C. §102 –

Claims 1, 3, 4, 7, 8, 12 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by Hale *et al.* (U.S. Pat. No. 5,607,691). In making this rejection, the Office Action asserts that this reference teaches each element of the claimed invention. The applicants respectfully disagree and request reconsideration of this rejection.

Independent claim 1 recites in part:

> predicting an *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data....

Similary, independent claim 5 recites in part:

> predicting a simulated *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data....

Hale *et al.* appears to teach *in vitro* screening of a library of chemical modifiers for transport activity (see col. 31, lines 45-55). This *in vitro* screening data is used to identify the optimal chemical modifier (see col. 31, lines 60-61).

However, Hale *et al.* fails to use the *in vitro* data to predict an *in vivo* absorption profile or predict a simulated *in vivo* absorption profile. Hale also fails to disclose and/or suggest using initial dose data. Consequently, Hale *et al.* fails to teach and/or suggest either "predicting an *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data" or "predicting a simulated *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data".

Claims 1 and 5 also recite:

> selecting a predetermined absorption profile;

Applicants have carefully reviewed Hale *et al.* and could find no teaching and/or suggestion of "selecting a predetermined absorption profile."

Claims 1 and 5 further recite:

> producing a secondary compound library comprising test samples whose absorption profiles are better than or equivalent to the predetermined absorption profile

Not only is there no mention in Hale *et al.* of generating either an *in vivo* or a simulated *in vivo* absorption profile from initial dose data and from *in vitro* bioavailability data but there is also no mention of using these generated absorption profiles for screening a primary compound library or portion thereof. Rather, Hale *et al.* describe a drug delivery system (see Abstract and claim 1). The Screening Procedures (columns 31 and 32) merely mention standard generic screening procedures, which are known to have many problems including ineffectiveness and inefficiency (see present application, pages 4 and 5). Contrary to the examiner's understanding, columns 44 and 45 only disclose *in vitro* testing and *in vivo* delivery of pharmaceutical agent-chemical modifier complexes, not screening using the claimed absorption profiles.

Therefore, Hale *et al.* fails to teach and/or suggest "producing a secondary compound library comprising test samples whose absorption profiles are better than or equivalent to the predetermined absorption profile."

Accordingly, Hale *et al.* fails to teach and/or suggest the claimed invention. Consequently, Applicants request reconsideration and withdrawal of the rejection of claims 1, 3, 4, 7, 8, 12 and 13 under 35 U.S.C. §102(b).

Rejection under 35 U.S.C. §103 –

Claims 1 to 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hale *et al.* taken with Yang *et al.* (Pharmacokinetics, Introduction to Biochemical Toxicology, Hodgson and Levi (Eds.), Appleton & Lange, Norwalk, CT, 1994, pp. 49-73) and in view of Jacobson *et al.* (U.S. Pat. No. 5,773,423). In making this rejection, the Office Action asserts that the combination of these references teach each element of the claimed invention. The applicants respectfully disagree and request reconsideration of this rejection.

As noted above, Hale *et al.* fails to teach and/or suggest either "predicting an *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data" or "predicting a simulated *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data". Hale *et al.* also fails to teach and/or suggest "selecting a predetermined absorption profile." And Hale *et al.* fails to teach and/or suggest "producing a secondary compound library comprising test samples whose absorption profiles are better than or equivalent to the predetermined absorption profile."

Neither Yang *et al.* nor Jacobsen *et al.* are cited for correcting these deficiencies of Hale *et al.* Applicants have reviewed both references and could find no teaching and/or disclosure that would correct the above deficiencies. Consequently, the combination of these three references fail to teach and/or suggest either "predicting an *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data" or "predicting a simulated *in vivo* absorption profile for each of said test samples from initial dose data and from *in vitro* bioavailability data". These

references also fail to teach and/or suggest "selecting a predetermined absorption profile." And these three references fail to teach and/or suggest "producing a secondary compound library comprising test samples whose absorption profiles are better than or equivalent to the predetermined absorption profile."

Thus, the combination of Hale *et al.* with Yang *et al.* and Jacobsen *et al.* does not teach or suggest all the claim limitations. Consequently, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-17 under 35 U.S.C. § 103(a).

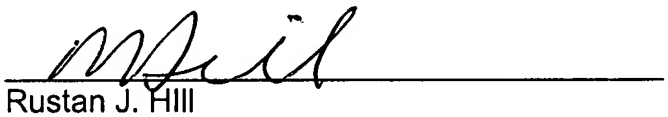
III. CONCLUSION

In view of the amendments and remarks above, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this paper is not timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees, which may be required with respect to this paper, referencing Attorney Docket No. 109904-00028.

Respectfully submitted,

ARENT FOX PLLC



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Declaration under 37 CFR 1.132